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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/697,785	10/30/2003	John D. Conroy JR.	21411-0001-1	8900

26587 7590 12/13/2006

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EXAMINER	
DIXON, ANNETTE FREDRICKA	
ART UNIT	**PAPER NUMBER**
3771	

DATE MAILED: 12/13/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/697,785	CONROY, JOHN D.	
	Examiner	Art Unit	
	Annette F. Dixon	3771	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26 September 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-12,14-19,27 and 51* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-6,9-12,14-19,27 and 51* is/are rejected.

7)☒ Claim(s) *7 and 8* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. This Office Action is in response to the amendment filed on September 26, 2006. Examiner acknowledges Claims 1-12, 14-19, 27 and 51 are pending in this application, with Claims 13, 20-26, and 28-50 having been cancelled, and claims 8 and 27 having been amended, and claim 51 having been newly added.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

3. Claims 1, 2, 4, 5, 9-11, 15, 17, 18, and 51 are rejected under 35 U.S.C. 102(e) as being anticipated by Hill et al. (6629525).

As to Claim 1, Hill discloses a system for avoiding hypoxemia in at least one subject exposed to a reduced atmospheric pressure, the system comprising: an air source (100) to supply an oxygen mixture to at least one subject; a microprocessor (160) being configured to determine an increased risk of hypoxemia in the at least one subject (by sensor 156) and atmospheric conditions corresponding to hypoxemia in the at least one subject (by sensor 158), the microprocessor activating the air source to

provide the oxygen mixture to the at least one subject in response to a determination of the increased risk of hypoxemia or atmospheric conditions corresponding to the increased risk of hypoxemia in the at least one subject; a first sensor (156) to measure at least one physiological characteristic of the at least one subject, the first sensor transmitting a first signal to the microprocessor with the at least one physiological characteristic of the at least one subject; wherein the microprocessor determines the increased risk of hypoxemia in the at least one subject by comparing the at least one physiological characteristics of the at least one subject with a predetermined value for the at least one physiological characteristic of the at least one subject, the microprocessor determining the risk of hypoxemia in response to the at least one physiological characteristic of the at least one subject being less than the predetermined value for the at least one physiological characteristic. (Column 11, Lines 24-49, and Fig. 5).

As to Claim 2, please see the rejection of claim 1 and Column 11, Lines 24-49, which disclose the sensor (156) can be used to measure oxygen red cell saturation level.

As to Claim 4, please see the abstract, which discloses the system to be portable.

As to Claim 5, please see the rejection of claim 4; further, as the system is portable it is fully capable to be used in an aircraft especially because the altitude sensor's (158) ability to adjust the gas delivery to the at least one subject during environmental changes.

As to Claim 9, please see the rejection of claim 5; further, as an unpressurized cabin may simply disclose an aircraft that is on land, the differences in operation between a person on land and a person in a grounded aircraft should be minimal.

As to Claim 10, please see the rejection of claim 4.

As to Claim 11, please see the rejection of claim 1 and Column 11, Lines 24-49, which disclose the sensor (158) can be used to measure atmospheric conditions.

As to Claim 15, please see the rejection of claim 4, which discloses the device to be portable. Inherently, the portability of the device enables the at least one subject to be in one location and the device to be in another location and still maintain the effectiveness of the machine provided that both the at least one subject and the device are exposed to similar environmental conditions and the gas delivery tube is long enough to reach the at least one subject. Further the portability of the device does not disclose that the device must be directly attached to the at least one subject; thereby enabling the device to be remote from the at least one subject.

As to Claim 17, the system of Hill et al. discloses a warning device (111) for providing a signal to the at least one subject in response to receiving a signal from the microprocessor (160). (Fig. 5).

As to Claim 18, please see the rejection of Claim 17; further, the signal is associated with the user interface and thus provides a visual signal to enable the at least one subject to enter data and control the oxygen output of the system.

As to Claim 51, please see the rejection of claim 11. As discussed the altitude sensor (158) measures the flight data or atmospheric conditions of the at least one subject to determine the gas delivery rate.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. Claims 3 and 27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hill et al. (6629525) in view of Tripp Jr. et al. (US H1039).

As to Claims 3 and 27, Hill discloses a system comprising all the elements recited in Claim 1, yet does not expressly discloses the predetermined value for the oxygen red cell saturation level to be about 91 percent. However, the disclosed oxygen saturation level was known at the time the invention was made. Specifically Tripp teaches the effects of oxygen saturation depletion in patient and a desire to maintain oxygen saturation levels between 86 and 95 percent, if not higher, to avoid the distress associated with oxygen depletion. (Column 10, Lines 33-58). Therefore, it would have been obvious to one having ordinary skill in the art to modify the device of Hill to operate at values around 91 present because it is well known in the art, as taught by Tripp, as a point in which the effects of oxygen depletion can be corrected prior to loss of cognitive mental ability or loss of consciousness.

6. Claim 12 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hill et al. (6629525) in view of Zysko (6452510).

As to Claim 12, Hill discloses a system comprising all the elements recited in Claim 11, yet does not expressly discloses the atmospheric pressure is measured in linear units mean sea level. However, at the time the invention was made, it was well known for atmospheric pressure to be measured in linear units mean sea level. Specifically, Zysko teaches the use of a device for determining the concentration and other ambient conditions in an airplane cabin for the purpose of warning the user of low air pressure in the cabin which may result in incapacitation and damage to the nervous system. Further Zysko measures the pressure altitude in mean sea level. (Column 1, Lines 25-40). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the device of Hill to include the ability to monitor the altitude in linear units mean sea level to provide a warning to the user of a potential hypoxic situation.

7. Claims 6, 14, 16, and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hill et al. (6629525) in view of Schmidt et al. (2006/0213519).

As to Claims 6 and 19, Hill discloses a system comprising all the elements recited, yet does not expressly disclose the affirmative act to reset the first time reference. However, at the time the invention was made the affirmative act by the at least one subject to reset the first time reference was known. Specifically, Schmidt

teaches a gas delivery system wherein the device keeps track of the total amount of the time the patient was in a hypoxic state and enables the user to access and reset the data via the user interface (32); thereby, enabling better patient safety and control. (Paragraph 0122). Therefore, it would have been obvious to one having ordinary skill in the art to modify the device of Hill to include the time monitoring system of Schmidt for the purpose of enabling better patient safety and control during the operation of the device.

As to Claims 14 and 16, Hill discloses a system comprising all the elements recited, yet does not expressly disclose a third signal connected to the microprocessor enabling the transmission of stored data to the microprocessor. However, at the time the invention was made the use of a storage device used in combination with a microprocessor was well known. Specifically, Schmidt teaches a gas delivery system that measures the blood oxygen content level in a patient and then compares the current data to the prior data. This comparison of the current data to the prior data enables a determination to be made as to what treatment is required for the patient. Intrinsically, the vary nature of this comparison system includes a storage device to retain the prior data. Specifically regarding claim 16, please see the rejection of claim 15 for the discussion of the word "remote". (Figure 3b). Therefore, it would have been obvious to one having ordinary skill in the art to modify the device of Hill to include the taught elements of Schmidt for the purpose of enabling a determination to be made of the effectiveness of the treatment to prevent a hypoxic event.

Double Patenting

8. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

9. Claims 1-12, 14-19, 27, and 51 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over *claims 20, 22, 23, 25, 26, 51-60 of copending Application No. 10/419672.* Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the instant application as currently amended are coextensive with the claims of the copending application. If these claims as currently written were presented to the Office the restriction requirement in the Office Action mailed May 26, 2006 would not have been required. This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

As to Claims 1-12, 15, 17-19, 27 and 51 (of the instant application), all the limitations can be found in *Claims 22, 23, 56-60 of the copending application '672*. As to Claims 14 and 16 (of the instant application), all the limitations can be found in *Claim 20, 25, 26, 51-55 of the copending application '672*.

Allowable Subject Matter

10. Claims 7 and 8 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Response to Arguments

11. Applicant's arguments, see Pages 8-26, filed September 26, 2006, with respect to the rejection(s) of claim(s) 1-12, 14-19, 27 under 35 U.S.C. 102 (b) have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of Hill et al. (6629525) under 35 U.S.C. 102(e).

Conclusion

12. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. The balance of art listed by US patent number below, shows additional inventions in the field of systems for avoiding hypoxemia.

Curry et al. (5,791,982)

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Annette F. Dixon whose telephone number is (571) 272-3392. The examiner can normally be reached on Monday thru Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Justine Yu can be reached on (571) 272-4835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

TEENA MITCHELL
PRIMARY EXAMINER

Annette F Dixon
Examiner
Art Unit 3771
December 7, 2006